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10/022,343	12/20/2001	Ratan K. Chaudhuri	EMI 29	2576

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EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/06/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,343

Applicant(s)

CHAUDHURI, RATAN K.

Examiner

Hector M Reyes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 to 90 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15, 39, 41, 43, 45, 47, 82-85 and 86-88 is/are allowed.
- 6) ☒ Claim(s) 2, 3, 5, 8 to 38, 40, 42, 46, 48 to 51, 53 to 81, 89 and 90 is/are rejected.
- 7) ☒ Claim(s) 4, 6, 7, 44, 46, 48 and 52 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Paper Entry

Examiner acknowledges the following Papers:

- Applicant's Amendment, filed on May 6, 2003 as Paper no. 12
- Applicant's Supplemental Amendment filed on June 11, 2003 as Paper no. 13.

Status of The Claims

Claim 1 had been canceled. Claims 2, 3, 4, 11, 15, 16, 17, 18, 20, 21, 24, 27, 28, 29, 30, 31, 32, 34, 37, 39, 43 and 47 had been amended. New claims **51 to 90** had been added. Currently, claims 2 through 90 are under Examination.

Rejection Modified in view of Applicant's Amendment

Claims 2, 8 to 12, 14, 16 to 38, 40, 42, 46, 48-51, 53 to 55, 57 to 81, 89 and 90 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

- Claims 2, 8 to 11, 12, 14, 34 to 38, 51, 53 to 55, 57 to 65 are drawn to compounds, wherein the variable X is defined as oxygen or nitrogen X=O, NH. While the specification provides support for the preparation and used of compounds wherein X is oxygen-as ester~~s~~ derivatives~~s~~ of cinnamic and malonic acid- there is no support for the preparation of compounds wherein the said variable X is nitrogen, NH nor for the use of such nitrogen bearing derivatives in methods or formulations.
- Claims 16 to 33, 40, 42, 44, 46, 48-50, 61 to 81, 89 and 90 are drawn to methods of using or formulations prepared from the compounds claimed above. Therefore,

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the availability of such compounds is an **essential element** in the said methods or formulations. There is no specific utility for those instances mentioned above because there is no indication of how to prepare the compounds embraced by the claims wherein the X variable is N.

Claims 2, 8 to 11, 12, 14, 16 to 33, 34 to 38, 40, 42, 46, 48-50, 51, 53 to 55, 57 to 81, 89 and 90 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 8 to 11, 12, 14, 34 to 38, 51, 53 to 55, 57 to 65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein the X variable is oxygen-as ester~~s~~ derivatives~~s~~ of cinnamic or malonic acid-, does not reasonably provide enablement for the preparation and use~~d~~ of compounds wherein such variable is nitrogen (NH). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Claims 16 to 33, 40, 42, 44, 46, 48-50, 61 to 81, 89 and 90 drawn to methods of using or formulations prepared from the claimed compounds are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein:

- X variable is oxygen-as esters derivatives of cinnamic or malonic acid-, does not reasonably provide enablement for the preparation and use of compounds wherein the compounds having as the X variable nitrogen (NH).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, **to make and use** the invention commensurate in scope with these claims. Therefore, the availability of such compounds is an **essential element** in the said method or formulations.

The crucial factor in the lack of enablement indicated above rest in the availability and identification of the required and claimed compounds. The determination of lack of enablement is achieved after consideration of the factors discussed below from where it is concluded that undue experimentation would be required for those skill in the art in order to make and use the invention as being claimed. See In re Wands, 858 F2d, 731 8 USPQ 2d 1400 (1988).

The Breadth of the Claims

Regarding the breadth of the invention, the Examiner hereby incorporated commentaries found in the International Search Report for PCT EP02/06743 wherein it

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is indicated that such claims "relate to an extremely large number of possible compounds, formulations containing them or uses thereof".

Clearly, the number of compounds is quite extensive. Moreover, such definition of compounds in the said claims embraces **compounds for which the disclosure does not present a method of preparation.** Indeed, there is not even **a single compound,** which is not an ester derivative of cinnamic or malonic acid. If such compounds or its preparation method are not disclosed, how methods or using the same or compositions or formulation comprising the same can be prepared? Allowance of such compound claims or method of using the same or compositions comprising those compounds **would obscure a whole area of research without providing any benefit to the public.**

The Nature of the Invention

The nature of the invention: organic compounds and method of using the same demands the disclosure of new compounds and its method of preparation in such a case that a person skill in the art can make and use the invention. In the present case some of the compounds embraced by the claims and its method of preparation are disclosed in the specification. However, such disclosure is not adequate to prepare other compounds that although embraced by the claims, are not malonic or cinnamic acid derivatives. For example, claim 38 is specifically drawn to derivatives as described in claim 3, wherein X value is nitrogen. Such compounds, its method of preparation, uses or formulations comprising the same are not disclose in the specification.

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The task of preparing a chemical compound, alone its a very demanding one, specially in the case that not even the starting materials are indicated.

Such preparation would require the determination of those adequate reactions conditions and parameters. The preparation of other derivatives different from such specific esters would required a lot of time and effort directed to the preparation of such compounds and after its synthesis and purification, to prepared the claimed compositions or method of using the same. Clearly, undue experimentation would be required.

The Existence of Working Examples

Applicant's disclosure only provides as examples ester derivatives of cinnamic or malonic esters.

There is no disclosure of how to prepare any other type of compounds as indicated in the Reaction Pathway on page 19 of the specification and in the specific examples base on such reaction pathway.

Predictability in The Art

Each chemical compound requires a specific method of preparation with its specific reaction conditions and it is very unlikely that the same method can be use to prepared compounds with different chemical structures or functional groups. Such method would need to be determined by experimentation.

On the other hand, the electronic nature of the chemical structure also is intrinsic to the compound itself and further experimentation would be required in order to prepare the claimed compositions of methods with compounds that are not embrace by the

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disclosure even though are embraced by the claims. Therefore, considering the above factors, it is clear that a person skill in the art would need to carry out undue experimentation in order to make and use the invention as being claim.

Rejections Withdrawn

- Rejection of Claims 2, 3 and 4 under 35 U.S.C. 102(b) as being anticipated by DE_2816819 A1 is hereby withdrawn in view of Applicant's Amendment of said claims.
- Rejection of claims 2, 3, 34 and 37 under 35 U.S.C. 102(b) as being anticipated by Kawamoto, EP 0631177 is hereby withdrawn in view of Applicant's amendment of such claims.

New Rejections in view of Applicants Amendments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 5, 11 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Shirodkar et al, Indian J. of Heterocyclic Chemistry, (1996) 6 (2) pp155-156, HCAPLUS document number 126:171460

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Shirodkar discloses:

- Butanoic acid, 2-[(4-hydroxy-3-methoxyphenyl)methylene]-3-oxo-,methyl ester, registry number 187245-33-6
- Butanoic acid, 2-[(4-hydroxy-3-methoxyphenyl)methylene]-3-oxo-,ethyl ester with registry number 89082-79-1
- Butanoic acid, 2-[(3-ethoxy-4-hydroxyphenyl)methylene]-3-oxo-,methyl ester, with a registry number 187245-34-7
- Butanoic acid, 2-[(3-ethoxy-4-hydroxyphenyl)methylene]-3-oxo-,ethyl ester, with a registry number 187245-35-8.

Claims 12, 13, 55 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al, Polym. Prep. (AM. Chem. Soc. Div. Polym. Chem.) 1987, 28 (1), pages 207-208, HCAPLUS document number 106:214481.

Green discloses:

- 2-propenoic acid, 2-cyano-3-(4-hydroxy-3-methoxy-5-methylphenyl), methyl ester, registry number 108433-13-2.

Claims Objected

Claims 4, 6, 7, 44, 46, 48 and 52 are objected because the said claims depend, directly or indirectly on rejected claims.

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Allowabl Subj ct Matter

Claims 15, 39, 41, 43, 45, 47, 82, 83, 84, 85, 86, 87 and 88 drawn to a series of specific esters of cinnamic and malonic acids or its further use in compositions and methods are allowed. Such derivatives or its methods of use were not found disclosed in the prior art of record.

Response to Arguments

Applicant's arguments filed on May 6, 2003 have been fully considered but they are not persuasive. Applicants claim that the Office Action alleges that that compounds having an NH group as X are not enable because:

- The specification does not exemplify a compound wherein X is NH.
- The preparation of said compounds are routine for one of ordinary skill in the art and thus, their synthesis methods/protocols need not be described in the specification.
- A patent need not teach, and preferably omits, what is well known in the art
- No undue experimentation is necessary for one skill in the art to prepare these compounds
- Applicants present copy of the article Novel Caffeic acid derivatives as published by J med. Chem. 1991, 34, pp1503-1505, and points the Examiners attention to Compound #5, Table 1.

The said arguments are not found persuasive because:

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- The enablement rejection is based upon **multiple factors** already presented in the previous Office Action, and not merely upon the fact that there are no examples of compounds having NH as the X variable.
- If the said compounds, as Applicants argue are within the domain of the one skill in the art, and if they can readily be prepared by those skilled in the art as a routine practice, Where is the novelty required for the embodiment of the instant invention embracing the said compounds?
- The said compounds are not known in the art, therefore are not within the knowledge of what has been called "well known in the art".
- The presented copy of the article Novel Caffeic acid derivatives as published by J. med. Chem. 1991, 34, pp1503-1505, and the Compound #5, Table or other compounds disclosed in the said references are not embraced by the compounds being claimed in the instant invention, therefore the said reference does not cure the lack of enablement.
- The lack of enablement is directed to **essential elements of the invention**: preparation, isolation and characterization of novel compounds that are claimed and its further use in different methods, which are also claimed.

In view of the arguments hereby presented it is concluded that there is a clear lack of enablement in the invention as claimed and that a patent to such compound claims or method of using the same or compositions comprising those compounds would obscure a whole area of research without providing any benefit to the public.

CONCLUSION

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Hector M Reyes Ph D JD

August 1, 2003